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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,763	06/18/2001	K. Roger Aoki	16952CON1DIV8DIV3	3611

7590

04/20/2004

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EXAMINER
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CHISM, BILLY D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/883,763

### Applicant(s)

AOKI ET AL.

### Examiner

B. Dell Chism

### Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21,38,41 and 51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,38,41 and 51 is/are rejected.
- 7) ☒ Claim(s) 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12-23-2002.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

Applicant's election with traverse of Group VIII, claims 21, 38, 41 and 51, in the last office action filed 29 December 2003, is acknowledged. The traversal is on the ground(s) that since all restricted inventions are drawn to use of the same compound that in would pose a burden on the examiner to perform the search. This is not found persuasive because each invention is drawn to a difference patient population requiring different method steps for use of the compound to be used leading to different end results. Thus, a search of the elected invention would not necessarily be inclusive of a search of the other inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claims 21 and 38 are generic to each of the inventions of the last office action. Therefore, these claims were only examined to the extent they pertained to the elected invention, i.e., treatment of lower back pain. At the time of Allowance, Applicants will be required to cancel all nonelected subject matter.

***Claim Objections***

1. Claim 38 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 38 is drawn to a nonelected claim, however, under the restriction in the last office action the claim 38 should be drawn to claim 21.

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*Specification*

2. The disclosure is objected to because of the following informalities: page 1 of the specification contains a Cross Reference section wherein the status of those documents listed must be updated.

Appropriate correction is required.

*Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 21, 38, 41 and 51 rejected under 35 U.S.C. 103(a) as being unpatentable over Borodic (US 5,183,462) and Davis *et al.* (Movement Disorders: Official Journal of the Movement Disorder Society, 1993, Vol. 8, No. 3, page 371, abstract only).

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Borodic teaches the controlled administration of chemodenervating pharmaceuticals such as botulinum toxin types A-G, wherein the type selected retains “the native form’s ability to block acetylcholine release” (column 3, lines 58-61) in the neuromuscular junction.

Furthermore, Borodic discusses the mechanism by which the botulinum toxin works; “a sufficient dose of the toxin acts on striated muscle to block release of the acetylcholine neurotransmitter from the presynaptic membrane resulting in varying degrees of effective denervation of the muscle in regions contacted by the toxin. This results in an increase in post-synaptic acetylcholinesterase activity and an increase in the population of acetylcholine receptors, effects which occur as a characteristic physiological response to denervation. After a period of days, the axon terminals develop sprouting, and over a period of several months, collateral motor axons establish new neuromuscular connections with the muscle fiber. As neuromuscular junctions are regenerated, full function of the muscle returns along with the spasmodic contractions or hyperstimulation symptomatic of the disease.” Borodic achieves this by suggesting direct injection into the striated muscles.

Davis *et al.* teach that botulinum toxin type A “reduced the tone of paraspinal and thigh muscles significantly and resulted in marked improvement of ambulation and cessation of pain.” (see abstract at page 371)

Borodic does not teach the specific treatment of striated muscles in the lower back for management of back pain, and Davis *et al.* does not teach the use of botulinum toxin type b for the treatment of lower back pain. However, it would have been obvious to one of ordinary skill in the art at the time of the present invention to combine the two for use of botulinum toxin type B for the treatment of pain in striated muscles of the lower back. Although Davis *et al.* teaches

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toxin type A, Borodic clearly demonstrates that any of the botulinum toxin types can be used as long as the native compounds ability to block acetylcholine is maintained. Thus, it would be obvious to use type B for the teachings of Davis *et al.* wherein striated lower back muscles are experiencing pain. Furthermore, it would be obvious to use the type B for lower back pain related to muscle damage wherein the muscle remains intact, but the pain is one of spasticity, e.g., a muscle spasm in a condition secondary to a sports injury.

### ***Conclusion***

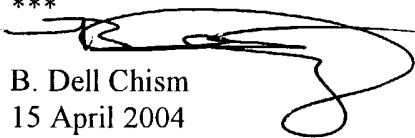
No claims are allowed. Claims 21, 38, 41 and 51 are rejected and claim 38 objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism whose telephone number is 571-272-0962. The examiner can normally be reached on 7:30 AM - 4:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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B. Dell Chism  
15 April 2004



CHRISTOPHER R. TATE  
PRIMARY EXAMINER